

Remarks

With this response, Claims 1-41 are pending, of which claims 16-18, 21-23, and 38-40 are withdrawn from consideration as being drawn to non-elected species. However, Applicants reserve the right to have the withdrawn claims examined upon indication of a allowable generic claim. Support for these amendments can be found throughout the claims and specification as originally filed, *e.g.*, in original claim 24.

I. Examiner Interview

Applicants thank Examiners Jiang and Spector for their courtesy during the Interview on March 1, 2004 (“Interview”). In attendance at the Interview were Examiners Jiang and Spector, Applicants’ representatives Molly Holman and Milan Vinnola, and Inventor Orville Kolterman. During the Interview, Applicants, in part, discussed the physiology of plasma lipids generally, the teachings of Beeley *et al.*, and the understanding of one of skill in the art with regard to the specificity and timing of measuring plasma triglyceride levels based on the teachings of the cited art.

During the Interview, it was agreed that the cited art did not teach or suggest the measurement of postprandial triglyceride levels to identify a patient in need of lowering of plasma triglycerides.

II. Rejection under 35 U.S.C. § 102(b)

Claims 1, 3, 5, 6, 9-14, 19, 20, 24, 26, 28, 29, 32-36 and 41 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Beeley *et al.*, WO 98/30231 (hereinafter “Beeley”), and as evidenced by Beers *et al.*, the Merck Manual, 17th edition, pages 200-203 (hereinafter “Beers”). This rejection is respectfully traversed and reconsideration is requested for at least the reasons that follow.

The Examiner acknowledges that “Beeley does not specifically mention the term ‘triglyceride,’” but contends that “Beeley’s method for lowering plasma lipids would inherently lower the triglyceride levels.” Office action mailed December 2, 2003 at page 6. Applicants respectfully disagree.

Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744,

747 (Fed. Cir. 1987). However, a prior art reference may anticipate a claim without expressly disclosing a feature of the claimed invention if that missing feature is necessarily present, or inherent, in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). In this regard, inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure if “the result is a necessary consequence of what was deliberately intended.” *Mehl/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1366 (Fed. Cir. 1999), *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002).

The Examiner asserts that it is well known in the art that the major plasma lipids are cholesterol and triglycerides and that cholesterol and triglycerides are measured by separate methods (citing Beers, pages 200, 202, and 203), so that a person of ordinary skill in the art would understand “lowering plasma lipids” to require measuring *both* cholesterol and triglyceride levels in order to determine whether the plasma lipid levels of a subject are elevated prior to administering exendins. Office Action mailed December 2, 2003 at page 3. Applicants respectfully disagree. Applicants submit that this assertion oversimplifies the current knowledge in hyperlipidemia. Given the complexity of and lack of consensus within plasma lipid research (see Beers), one skilled in the art would not “at once envisage” that “lowering plasma lipids” disclosed in Beeley would contemplate lowering triglycerides specifically as a natural consequence of what was deliberately intended. See *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962); M.P.E.P. § 2131.02.

Nonetheless, in order to facilitate prosecution, each of the independent claims has been amended to recite that the subject to be treated has elevated postprandial triglyceride levels, *i.e.*, postprandial triglyceride levels which are elevated compared to the normal range of postprandial triglyceride levels. As acknowledged during the Interview, the cited art does not teach or suggest measurement of postprandial triglyceride levels to identify a subject in need of treatment. As such, the cited art does not teach each and every limitation of the independent claims.

For at least the foregoing reasons, it is respectfully submitted that the claims are novel over Beeley since, at a minimum, the reference does not disclose or suggest the

aforementioned limitations. As such, withdrawal of this rejection is respectfully requested.

III. Rejection under 35 U.S.C. § 103(a)

Claims 2, 4, 7, 8, 25, 27, 20 and 31 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Beeley. This rejection is respectfully traversed and reconsideration is requested for at least the reasons that follow.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure. See M.P.E.P. §§ 2143.01 and 2143.03.

As discussed above, Beeley does not discuss the use of exendins in the reduction of triglycerides specifically. Moreover, as acknowledged during the Interview, the cited art does not teach or suggest the measurement of postprandial triglyceride levels to identify a subject in need of treatment. As such, Beeley does not teach or suggest the identification of a subject with elevated postprandial triglyceride levels, followed by the administration of a therapeutically effective amount of an exendin or exendin agonist.

Claims 15 and 37 also stand rejected under 35 U.S.C. §103(a) as alleged being unpatentable over Beeley in view of Wagle et al. US 6,326,396 B1 (hereinafter "Wagle"). This rejection is respectfully traversed. For the reasons above, it is submitted that Beeley does not teach or suggest identifying a subject with elevated postprandial triglyceride levels and treating such subject with exendins or exendin agonists. Whatever else Wagle does disclose, it too does nothing to remedy the deficiencies in Beeley. As such, it is submitted that the claims are patentable over the cited art.

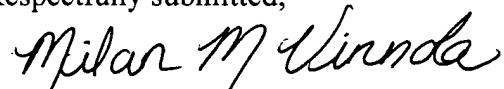
In sum, it is submitted that the prior art of record does not disclose or suggest the ability of exendins to specifically lower triglyceride levels, or suggest the identification of a subject with elevated postprandial triglyceride levels. As such, the cited references do not render the present claims obvious.

For at least the foregoing reasons, it is respectfully submitted that all of the pending claims are patentable over the prior art of record, since at a minimum they do not include or suggest the aforementioned limitations. As such, withdrawal of these rejections are respectfully requested.

Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-6111 should any additional information be necessary for allowance.

Respectfully submitted,



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